

ATTACHMENT 1

**STATEMENT OF WORK: "TECHNICAL SUPPORT FOR THE ASSESSMENT
OF THE ECOLOGICAL RISK OF PESTICIDES IN THE
ENVIRONMENT"**

Statement of Work (SOW)

Title: Technical Support for Assessment of the Ecological Risk of Pesticides in the Environment

BACKGROUND

EPA's Office of Pesticide Programs (OPP) as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996, is responsible for the regulation of pesticides through the registration, registration review and re-registration of pesticides. OPP develops data requirements and guidelines for the conduct of studies by registrants that are used, along with other data and information, to assess the potential impact of the use of the pesticide on human health and the environment. Before EPA can use studies and data in assessing risk, these data must be evaluated to determine their adequacy and validity and to ensure that appropriate quality assurance procedures were carried out. Once data have been evaluated and determined to be acceptable and valid, these data are used to assess risk to human health and ecological resources. OPP also convenes scientific workshops and seminars to discuss and resolve scientific issues associated with the registration, registration review and re-registration of pesticides.

OBJECTIVE

The resulting Contract is expected to provide support primarily in the area of review and evaluation of available data pertaining to the eco-toxicity of pesticides (including the evaluation and summarization of ecological field and monitoring data). The contract will also provide support for the summarization of ecological effects data, researching of ecological effects issues and the development of science options for consideration by EPA, locating and retrieving documents and literature, reformatting data, and entering data into EPA databases and automated document systems.

The Contractor shall upon request through work assignments, collect data from open literature and/or from other sources designated by EPA and shall review these data as well as all other ecological toxicity studies provided to the Contractor by EPA. The reviews shall evaluate individual studies based on scientific soundness and guidance provided by EPA. The Contractor shall fully substantiate and document all analysis and conclusions so that EPA may critically analyze and approve/disapprove any recommendation, options, alternatives or courses of action flowing from the Contractor's work effort.

II. GENERAL REQUIREMENTS

A. FIFRA CBI

To perform Work Assignments under this contract, the contractor may require access to FIFRA Confidential Business Information (FIFRA CBI) submitted by pesticide registrants to EPA. Disclosure of FIFRA CBI to contractors is provided for under Section 10(e) of FIFRA and in 40 CFR 2.307. Consequently, the contractor must be cleared for access to FIFRA CBI and must control FIFRA CBI according to the requirements specified for contractors in the EPA publication, "FIFRA Information Security Manual", dated July 1988. Access of the contractor to FIFRA CBI is intermittent and will not require allocation of office space. If contractor works on-site, a CD or other media identify identification of contractor personnel will be verified by EPA.

Control measures for protecting FIFRA CBI shall be in accord with the following sections of the Security Manual:

- Disclosure of FIFRA CBI to contractors (section 3)
- Procedures for gaining access to FIFRA sensitive information (section 4) and
- Operational procedures for protecting FIFRA sensitive information (section 5).

The contract as written shall incorporate certain clauses that describe actions to be taken by the contractor with regard to FIFRA sensitive information; these clauses are contained in 40 CFR 2.301 (h)(23)(ii), and are Exhibit 6 in the Security Manual.

B. Other General Requirements

The Contractor will adhere to the following general requirements.

1. In performing the services required under this SOW, the Contractor shall submit all relevant information used in developing conclusions or options to the Project Officer (PO) for all projects for evaluation, review and approval.

2. All reports, drafts, papers, etc., prepared by the Contractor shall be submitted in paper form and in electronic form using a current version of WordPerfect or compatible software. It is possible the standard word processing software may change, in which case the Contractor will be notified in advance and allowed time to adjust their operating systems. The Contractor shall submit the completed draft to the Program Office for review and approval. The drafts submitted shall include copies of the literature cited or make reference to all citation in the document for Program Office verification and approval.

3. When in attendance at meetings, the Contractor's attendance shall be limited to that portion of the activity for which the Contractor is required in order to meet the requirements of the SOW. The Contractor personnel shall identify himself or herself as

contractor personnel in all activities associated with work performed under the SOW, and in attendance at meetings in conjunction with activities associated with the SOW requirements.

4. Reports submitted by the Contractor that contain recommendations to the EPA, e.g. in support of policy options, shall explain and rank alternatives, summarize the substance of deliberation; report any dissenting views; list the sources relied upon; and make clear the method and consideration upon which the recommendations are based.

5. The Contractor shall develop internal policies and procedures for ensuring that the Contractor's reviewers properly evaluate the assessment of the ecological risk of pesticides in the environments, and other required assessments. The Contractor shall institute Contractor staff training programs and shall submit copies of all internal policies, operating procedures, and training programs to the EPA within 2 months of the awarding of this contract.

6. The Contractor must communicate by telephone or email with the PO at least every other week to discuss/update the progress of the tasks. The contractor must provide on CD periodical compilations of completed work including both a cumulative set covering all work done during the contract, and a set of completions since the last compilation. This would likely be a quarterly activity, and would include all the DERs, Hazard Profiles and other products completed. The documents must be arranged in two folders, first the *recent completions* folder that contains the work done since the last update, second the *cumulative set*. The *cumulative set* would contain all the past completion plus the *recent completions*. When the documents are related to a chemical, the documents must be arranged in folders named by PC Code chemical name, eg 123456 chemname. If not associated with a specific chemical, the documents would be placed in folders by Task and be named by work assignment.

7. Unless otherwise specified in this contract, the Contractor shall not engage in nor subcontract for, any printing (as the term is defined in the Title I of the Government Printing and Binding Regulations in effect on the effective date of this contract) in connection with the performance of work under this contract. Printing is allowed for less than 5,000 units of only one page and less than 25,000 units in the aggregate of multiple pages. The contractor may perform a requirement involving the multi-color duplication of no more than 100 pages in the aggregate using color copier technology, so long as such pages do not exceed the maximum image size of 10 and 3/4 inches by 14 and 1/4 inches in size. Duplication services below these thresholds are not considered printing.

8. Contractor must adhere to all the provisions stated in EPAAR 1552.209-71 "Organizational Conflict of Interest," EPAAR 1552.209-73 "Notification of Conflicts of Interest Regarding Personnel," EPAAR 1552.210-80 "Annual Certification," EPAAR 1552-210-81 "Update of Conflict of Interest Plan," and EPAAR 1552.227-76 "Project

Employee Confidentiality Agreement.” The RFP and contract will contain Conflict of Interest (COI) provisions and clauses to allow the EPA to avoid actual or potential conflicts of interest. These provisions will require (1) contractors offering bids to submit conflict of interest avoidance plans as part of these proposals, and (2) the contractor to alert EPA to actual or potential conflicts of interest with respect to individual work assignments.

9. Any training aid, database, checklist or other system or shell, whether in electronic or in hard copy, that is developed by the Contractor in the process of performing the tasks under this contract, and the development of which is charged to the EPA Program Office, shall be made accessible to the EPA Program Office at the request of the Program Office, or at the termination of the contract, and will be the property of the EPA Program Office.

10. The Contractor will receive the final data package and/or assignment to complete an assessment or project no later than two months prior to the end of the contract Period of Performance.

C. Enhanced Review

Under Section 33 of FIFRA (as added by subsection (f)(2) of the Pesticide Registration Improvement Act of 2003), the EPA will collect fees from registrants to register their pesticide chemical for review. The benefit of this Fee is to guarantee the registrant that the time frame for registering their chemical will be reduced.

This contract shall require the contractor, on occasion, to perform an enhanced review of some pesticide chemicals, regardless of the current workload. **The contractor shall receive a separate work assignment for this type of review which will be processed as a Performance-Based work assignment.** This work will be funded with new appropriated funds associated with the Act. Along with the enhanced review of the pesticide chemical, the contractor shall also be required to track the hours and dollars associated with this work assignment separately. As in a Performance-Based task, the contractor shall receive an incentive dependent upon the percentage of work that is completed by the requested due date, and a disincentive if the task is not complete by the requested time allowed.

Method of Surveillance for Task 1, 2, 5 and 6 under Performance - Based work Assignments

Reports prepared by the contractor undergo a secondary review process in OPP/EFED. The EFED reviewers examine the conclusions drawn by the contractor and complete delivery acceptance summary form that note the major discrepancies, omissions, inaccuracies and / or inappropriate data evaluation. The project manager will compare Agency due dates or approved revised due dates to completed date of

reports, quarterly and calculate the percentage of late reports. The project manager will compare approved technical review hours with total technical review hours charged for each task by the contractor, quarterly and calculate the percentage of technical review hours over the Agency approved amount.

Acceptability Quality Limit for All Eco Tasks

No more than an average error of 5% per quarter considered as some major discrepancies, omissions, inaccuracies and/or inappropriate data evaluation is acceptable per quarter. Ninety five percent of reports per quarter are to be accurately completed within the Agency approved time frame. Ninety nine percent of the technical review hours charged by contractor per quarter are to be in accordance to the Agency approved technical review hours per task.

Disincentive for Task 1, 2, 5 & 6

A 2% reduction per quarter if more than 5% major discrepancies, omissions etc. A 1% reduction per quarter if, more than 5% of reports per quarter are not completed with the Agency approved time frame. A 3% reduction if more than 1% of the technical review hours per quarter exceed the approved amount.

SCOPE OF WORK

As specified in individual work assignments, the Contractor shall provide scientific reviews and evaluations to EPA on the ecotoxicity of pesticides in connection with Reregistration, Registration, Special Review, and Special Assignments as exemplified in the tasks described below.

The Contractor shall review and evaluate ecotoxicology data to support environmental assessment for pesticides. Generally data to be reviewed are provided by EPA, and usually relate to one chemical. The available data will be provided as paper or electronic versions of studies submitted by registrants, conducted by governmental, private or academic institutions, or obtained from scientific publications. The Project Officer will transmit all data associated with work assignments to the Contractor by a registered, return receipt, rapid mail system commensurate with the confidential nature of the information.

Occasionally, in addition to data evaluation the contractor may be requested to perform other ecological related assignments as specified in --Task 3; summarize incident reports of pesticide poisoning to non humans -- Task 4; construct data base and perform data entry and --Task 5; perform special assignments related to various effects issues including but not limited to, endangered species assessments, literature searches, and retrieval of hard copies, data summarization and reformatting etc.

The basic procedures used by the EPA in testing and evaluating ecological risk are described in the Pesticide Assessment Guidelines for fish and wildlife (Subdivision E) non-target insects (Subdivision L) and non-target plants (Subdivision J). These guidelines are available from NTIS* as noted below.

National Technical Information Service
ATTN: Order Desk
5285 Port Royal Road
Springfield, Virginia 22161

Pesticide Assessment Guidelines

NTIS Order Nos.

Subdivision E	B83-153908, PB86-248176, PB87-207700, PB88-117288
Subdivision J	PB83-153940
Subdivision L	PB83-153957, PB88-117296

DELINEATION OF TASKS

Task 1. Evaluation of Data (DERs)

The contractor shall evaluate studies provided by the EPA and provide a record of this evaluation in a Data Evaluation Review (DER) or other similar study evaluation report form or system, based on guidance provided by the EPA, and according to scientific judgement and knowledge the reviewing contractor staff is expected to possess relative to the kinds of studies to be reviewed under this contract. Specific formats and guidance for filling in each section of the format would be provided to the contractor, but generally, an evaluation for each study shall include the following: (1) Study identifying information, (2) an in-depth examination of the materials and methods employed; (3) an in-depth examination of the reported results; (4) an in-depth discussion of the reviewer's scientific assessment of the study; and (5) the reviewer's conclusions which summarize the overall conclusions and significance of the study.

The review and evaluation of each study shall include all necessary technical detail including graphic displays of data, summary tables, and a list of references needed to substantiate and communicate supporting the reviewer's conclusions. All DER's must be signed and dated. For each chemical, the data submitted may include any or all of the studies listed below.

Below is a rough estimate of the number of hours typically required to perform the activities that may be required for each task and sub task of this contract. Numbers refer to specific test guidelines published as part of the Pesticide Assessment Guidelines.

<u>Guideline No.</u>	<u>Study Title</u>	<u>Estimated Averaged Hours</u>
71-1	Avian Oral LD50	5
71-2	Avian Dietary LC50	5
71-3	Mammal Toxicity Test	5
71-4	Avian Reproduction Test	30
71-5	Simulated Field Test	40
71-5	Simulated or Actual Field Test	100
72-1	Acute Fish LC50	5
72-2	Acute Invertebrate LC50	5
72-3	Acute Testing for Estuarine/Marine organisms	5
72-4	Fish Early Life Stage	20
72-4	Aquatic Invertebrate Life Cycle	20
72-5	Fish Life-Cycle Test	40
72-6	Aquatic Organism Accumulation Test	25
72-7	Simulated or Actual Field Testing	120
122-1	Seedling Emergence/Vegetative Vigor-Tier 1	12
123-1	Seedling Emergence/Vegetative Vigor-Tier 11	30
122-2	Aquatic Plant-Tier 1	5
123-2	Aquatic Plant Growth-Tier 11	5 (per species)
141-1	Honey Bee Acute Contact LD50	5
141-2	Honey Bee-Toxicity of Residues	5

NOTE: Review of additional studies such as an acute aquatic invertebrate sediment bioassays, earthworm, other terrestrial insect, and other plant studies may be requested and the number of hours will be negotiated with the contractor at that time.

TASK 2. Hazard Profile or Ecological Effects Summary

The Environmental Fate and Effects Division (EFED) conducts ecological risk assessments on pesticides for their effects on non target organisms. Part of this assessment is the summarizing of effects data including lists of toxicity studies into a Hazard or Effects Profile for the purposes of showing the range of effects caused by the pesticide to plants and wildlife, and a description of such factors as study results and adequacy of the data. The Hazard or Effects Profile section may be called different things in different kinds of documents and/or the title of the section may change over the course of the contract, but generally it is a compilation of the tables and accompanying narratives of the ecotoxicological studies for a pesticide. The contractor shall include those studies that have been reviewed under Task 1, as well as any others that EPA has identified to be included in the Hazard profile. The Hazard or Effects Profile shall resemble the format provided by EPA. The format may be modified after

consultation with EPA. A bibliography of the studies will also be requested.

Work Plans shall be submitted by the contractor within reasonable time after the receipt of the work assignments.

The completed Hazard or Effects Profile shall be submitted in both hard copy and electronic format to EPA on or before the assigned date.

Task 3. Review of Incident Information.

The EPA occasionally receives information on the effects of pesticides on non-target organisms or pesticide residues in the environment. The contract shall provide a summary of the findings as well as an appraisal of the completeness of the report. The work assignment shall provide the level of detail expected in the final evaluation.

Task 4. Entry of data/information into OPP-provided databases.

Upon request of the EPA, the Contractor shall input data or information into established OPP databases or automated document application systems. The data/information might be abstracted from completed study evaluations or DERs, and/or from original studies or monitoring reports.

Task 5. Special Assignments

In addition to performing the tasks identified above, the Contractor may be asked to perform special assignments. These generally relate to assessment of effects data, review of protocols to determine or measure effects, or reviewing issues related to effects to fish or wildlife, habitat, and/or endangered species. Other assignments might relate to the development and/or revision of protocols, guidelines and standard evaluation procedures. Such assignments might include literature searches and subsequent analysis and summarization, tabulation or extraction of data from, the retrieved articles. It might require the Contractor, on occasion, to conduct literature research to understand science issues, hold, facilitate and document scientific workshops, and conduct analyses of issues and provide science options.

Task 6. Enhanced Review as stated above in Section C.